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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/652,493	08/31/2000	Mina J. Bissell	IB-1398	3653

7590 07/24/2003

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[REDACTED] EXAMINER

YU, MISOOK

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1642

DATE MAILED: 07/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/652,493	BISSELL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 02 May 2003.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-8, 22-24, 29 and 30 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-8, 22-24, 29, and 30 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

### **DETAILED ACTION**

Claims 1-8, 22-24, 29, and 30 are pending and examined on merits.

The Office confirms all rejections not repeated in the previous Office action (Paper No. 10) were all withdrawn.

#### ***Claim Rejections - 35 USC § 112***

The rejection of claims 1-8, 22-24, 29, and 30 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn because applicant argument is persuasive.

Claims 1-8, 22-24, 29, and 30 remain rejected for reason of record under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's argument and Dr. Campisi's Declaration supporting applicant's assertion that the claimed invention is enabled have been fully considered but found unpersuasive because applicant has not submitted an objective evidence demonstrating a correlation between shedding of alpha-dystroglycan in vivo and cancer risk (potential tumorigenicity and/or tumor growth).

The Office agrees with applicant that the assay detecting of alpha-dystroglycan fragments, and determining calibration curves are routine. However, the Office maintains that undue experimentation is required for assessing whether detection of alpha-dystroglycan fragments correlates with tumor growth and potential tumorigenicity because it requires analysis of large quantity of clinical samples to determine whether or not shedding of said fragments occurs at all in vivo and detection of said shedding is indicative of tumor growth and potential tumorigenicity. Applicant argues in vivo demonstration and/or a working example is not necessary because the specification provides evidence dystroglycan as a tumor suppressor as shown in nude mice and 3D-BM assays. However, this argument is not commensurate in scope of the claimed invention because the invention is directed to method of determining whether one has tumor growth or cancer risk by detecting shedding of alpha-dystroglycan in blood.

Restoring function of dystoglycan protein by over-expressing said protein in vitro cells and nude mice reverses tumorigenic phenotype does not correlate determining whether one has tumor growth or cancer risk by detecting shedding of alpha-dystoglycan in blood. The publications submitted as Exhibit A-E do not show correlation between presence of alpha-dystoglycan fragments in blood and tumor growth and/or potential tumorigenity in vivo. Applicant is invited to submit evidence showing that detection of alpha-dystoglycan fragment in blood is correlated with tumor growth and/or potential tumorigenity in vivo in order to obviate this rejection.

The rejection of claims 22-24, 29, and 30 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn because applicant's argument is persuasive.

**Conclusion**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

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305-3014 for regular communications and 703-872-9307 for After Final  
communications.

Any inquiry of a general nature or relating to the status of this application or  
proceeding should be directed to the receptionist whose telephone number is 703-308-  
0196.

Misook Yu

July 23, 2003

Mary Mosher

MARY E. MOSHER  
PRIMARY EXAMINER  
GROUP 1800

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